Federation of American Hospitals

February 9, 2026

Via electronic submission at http://www.regulations.gov

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (CMS–5544–P)

Dear Dr. Oz:

The Federation of American Hospitals (FAH) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule updating Performance Year (PY) 2 of the Increasing Organ Transplant Access (IOTA) Model. As the national representative for over 1,000 tax-paying hospitals and health systems, including many kidney transplant programs that care for medically complex patients in urban, suburban and rural communities, FAH supports the overall goal of the IOTA Model to increase access to kidney transplantation while maintaining safe outcomes and improving patient experience. Kidney transplantation remains the best treatment option for most patients with end-stage renal disease, offering better survival, improved quality of life and lower long-term costs compared with long-term dialysis.[1] We also appreciate CMS's efforts to refine the model based on early experience and stakeholder feedback.

Because IOTA is a mandatory alternative payment model with two-sided financial risk, it is especially important that updates to the model are practical, technically sound and aligned with how transplant programs operate in the real world. In reviewing the proposed rule, FAH encourages CMS to consider the following recommendations:

- Ensure that participation rules support fair comparisons and meaningful evaluation by excluding facilities that do not operate under Medicare's payment system and by setting minimum transplant volume thresholds that avoid unstable results driven by very small numbers.
- Refine transplant volume targets to reflect real limits on transplant capacity, including staffing, operating room access, donor availability and post-transplant care resources. Targets based on short-term or peak performance may unintentionally discourage sustainable growth.
- FAH supports the use of risk adjusted modeling for graft survival outcomes and is encouraged by incorporating a model that supports access for higher-risk recipients and use of marginal organs. There is concern that differences between the CMS model and the Scientific Registry of Transplant Recipients (SRTR) model will create conflict. Transplant centers may face significant challenges balancing the incentives between the use of two different models.

[1] United States Renal Data System. (2023). USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.

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- Preserve strong financial incentives to support investments needed to expand transplant access. Reducing the maximum upside payment, without clear evidence that it will still drive participation, may weaken the model's effectiveness.
- Refine the patient notification requirements so they improve understanding without overwhelming patients or diverting clinical resources from direct care.
- Coordinate monitoring efforts with existing oversight programs, recognize real-world disruptions that affect transplant operations, and assess the combined administrative burden of model requirements.

IOTA Participants

CMS proposes to revise the eligibility criteria for IOTA participants by excluding Department of Veterans Affairs medical facilities and Military Medical Treatment Facilities beginning in PY 2. CMS explains that these facilities are not reimbursed under the Medicare inpatient prospective payment system and operate under distinct statutory, operational, and funding frameworks, which could complicate performance assessment and model evaluation.

FAH agrees with this proposed change. Including facilities that do not bill Medicare in the same manner as Medicare-participating makes it harder to compare performance and evaluate whether the model is working as intended.

CMS also proposes to increase the low-volume eligibility threshold from a minimum of 11 to a minimum of 15 kidney transplants performed annually during each baseline year. CMS states that this adjustment is intended to improve statistical reliability, protect beneficiary confidentiality and reflect experience suggesting that very low-volume programs may face disproportionate challenges complying with the model's reporting and operational requirements.

FAH supports this proposal. Kidney transplant outcomes and process measures are sensitive to small denominators, and very low-volume programs may experience volatility unrelated to true performance differences.[2] A slightly higher threshold supports a more stable and meaningful evaluation.

Performance Assessment

Achievement Domain

CMS proposes to continue assessing achievement performance based on each IOTA participant's kidney transplant volume relative to a participant-specific transplant target. CMS explains that this approach is intended to incentivize growth in transplant volume while accounting for historical performance and national transplant growth trends.

FAH understands this goal but remains concerned that transplant volume targets may not fully reflect real-world variability on transplant capacity. Kidney transplant capacity is constrained by multiple factors, including staffing shortages, operating room availability, donor organ supply, post-transplant infrastructure and the availability of specialized ancillary services.[3] Targets based on peak historical performance can set expectations that are not realistic year after year, especially when participation is mandatory and financial penalties apply.

FAH encourages CMS to further refine how targets are set so they reflect longer-term averages and real operational limits. More stable targets would support steady growth without discouraging participation or investment.

Quality Domain and Composite Graft Survival Rate

CMS proposes several changes to the quality domain, including the addition of risk adjustment to the composite graft survival rate. CMS explains that risk adjustment is intended to improve fairness by accounting for differences in recipient and donor characteristics that influence outcomes but are beyond a hospital's control.

FAH supports the inclusion of risk adjustment in principle. However, transplant centers may face significant challenges balancing the incentives created by the IOTA Model's CMS-administered risk-adjustment methodology

[2]Ashby, V. B., Port, F. K., Wolfe, R. A., & Leichtman, A. B. (2019). Transplant center volume and outcomes in kidney transplantation. American Journal of Transplantation, 19(3), 817–826.
[3] Hart, A., Smith, J. M., Skeans, M. A., et al. (2020). OPTN/SRTR annual data report: Kidney. American Journal of Transplantation, 20(S1), 20–130.

with the continued reliance of commercial payers on SRTR risk-adjusted outcomes for network participation and Center of Excellence (COE) designation.

While CMS has appropriately designed the IOTA Model to encourage increased transplant access, particularly for higher-risk recipients and marginal organs, commercial payers continue to rely heavily on Scientific Registry of Transplant Recipients (SRTR) program-specific reports as the primary benchmark for transplant quality. These SRTR reports are widely used to determine COE status, inclusion in narrow networks and eligibility for preferred reimbursement arrangements.

CMS proposes a set of recipient and donor variables that differ from established SRTR methodologies. As a result, transplant centers may experience competing and potentially conflicting incentives:

- Under IOTA, centers are encouraged to expand access and accept higher-risk recipients and donor organs, supported by CMS's risk-adjustment framework.
- Under SRTR-based commercial oversight, the same behavior may negatively affect reported outcomes, increasing the risk of adverse SRTR performance flags, or at least the perception that this may occur.

Loss or degradation of SRTR performance can have material downstream consequences, including:

- Loss of COE designation with commercial payers,
- Termination or non-renewal of commercial contracts,
- Reduced referrals from employer-sponsored and managed care plans, and
- Significant decreases in commercial transplant volume.

For many transplant programs, commercial volume represents a substantially larger share of total transplant activity and revenue than Medicare fee-for-service beneficiaries alone. Consequently, the financial and operational losses associated with diminished commercial participation may far exceed any upside incentives achievable under the IOTA Model, which applies to a limited Medicare FFS population.

This misalignment creates a real risk that:

- Programs may be forced to prioritize protection of SRTR metrics over participation in CMS's access-expansion goals.
- Centers may reduce overall transplant volume to mitigate reputational and contractual risk.
- The net effect could be fewer transplants performed overall, counter to the stated objectives of the IOTA Model.

A more effective and sustainable approach would be for SRTR reporting and oversight expectations to evolve toward alignment with the CMS IOTA Model, rather than requiring CMS payment policy to conform to existing SRTR frameworks.

CMS has articulated, through the IOTA Model, a clear policy objective: to increase transplant access while maintaining acceptable outcomes, particularly in the context of increasing clinical complexity, organ scarcity, and the growing reliance on donation after circulatory death (DCD) and other marginal kidneys. The CMS risk-adjustment framework reflects this objective by explicitly accounting for recipient and donor risk factors and by avoiding incentives that promote risk avoidance.

By contrast, SRTR program-specific reporting has historically emphasized outlier detection and survival optimization, often without sufficient accommodation for evolving clinical practice patterns. While appropriate for regulatory oversight, this approach can unintentionally discourage acceptance of higher-risk organs and recipients, particularly as transplant programs expand use of DCD kidneys, older donors and organs with complex donor characteristics.

Aligning SRTR reporting more closely with the CMS IOTA framework would provide an opportunity to reset expectations around outcomes in a manner consistent with contemporary transplant practice. Specifically, such alignment could:

- Shift performance evaluation from a narrow focus on survival optimization toward a balanced assessment of access, complexity and acceptable outcomes.
- Recognize that broader utilization of DCD and marginal kidneys is an intentional and necessary evolution of the transplant system, not a deviation from quality.
- Reduce the structural disincentives that currently discourage transplant centers from accepting organs that may carry higher short-term risk but substantial long-term benefits to patients and the healthcare system.
- Support transplant programs in expanding access without fear that access-oriented behavior will result in disproportionate reputational or contractual penalties.

Importantly, aligning SRTR toward the CMS model would help ensure that commercial payer expectations evolve in parallel with federal policy, rather than remain anchored to legacy benchmarks that no longer reflect the realities of organ availability or patient need. As commercial payers rely heavily on SRTR outcomes for COE designation and network participation, continued misalignment risks penalizing programs that are acting in accordance with CMS policy objectives.

Absent such alignment, transplant centers may face untenable trade-offs between:

- Participating fully in CMS's access-expansion goals under IOTA, and
- Protecting SRTR-reported outcomes necessary to maintain commercial contracts and referral networks.

These trade-offs could ultimately suppress overall transplant volume, particularly for higher-risk organs and recipients, undermining both CMS's policy goals and broader system sustainability.

CMS proposes to exclude multi-organ transplants from the composite graft survival measure, citing differences in clinical pathways and outcome expectations. FAH agrees with this proposal and recommends that all multi-organ transplants, including kidney–pancreas transplants, be excluded to ensure that the measure evaluates kidney-alone transplantation in a clinically meaningful manner.

Payment Methodology

CMS proposes reducing the maximum upside risk payment from $15,000 to $10,000 per transplant, effective in PY 2. CMS explains that this change is intended to recalibrate incentives based on early implementation experience and updated cost assumptions.

FAH is concerned that reducing the maximum upside payment weakens the financial signal necessary to support meaningful expansion of transplant capacity. Expanding transplant access requires sustained investment in specialized personnel, patient navigation, care coordination, data analytics and post-transplant monitoring. Evidence from other alternative payment models suggests that incentives must be sufficiently large and predictable to drive provider behavior change, particularly when participation is mandatory.[4]

Feedback from transplant programs indicates that the proposed reduction, when combined with increasing administrative and transparency requirements, may not adequately offset the costs associated with program expansion. In a labor-constrained environment, insufficient upside potential may discourage investments that are central to achieving the model's access goals.

[4] Song, Z., & Lee, T. H. (2020). The era of delivery system reform begins. JAMA, 323(14), 1343–1344.

FAH urges CMS to retain the current maximum upside payment level or to provide transparent empirical analysis demonstrating that the proposed reduction remains sufficient to sustain participation and investment across diverse transplant programs.

CMS also discusses the potential inclusion of Medicare Advantage (MA) beneficiaries in performance-based payment calculations but notes that, to date, statutory and operational considerations have limited inclusion to Medicare fee-for-service beneficiaries. FAH agrees that understanding this payment model in the context of including MA data would provide additional insights and enable comparisons between payors. However, any expansion must carefully consider the administrative burden, data availability and statutory non-interference requirements to avoid unintended disruption to existing contracting and referral arrangements.

Transparency Requirements

CMS proposes several transparency requirements, including public posting of waitlist selection criteria and living donor criteria, as well as semi-annual notifications to eligible Medicare beneficiaries regarding organ offers declined on their behalf. CMS states that these changes are intended to promote transparency and shared decision-making. FAH supports transparency goals and agrees that public posting can help patients understand transplant processes.

FAH has significant concerns regarding the proposed semiannual notification requirement related to declined organ offers. Organ offer decisions are complex, time-sensitive and highly individualized. Retrospective disclosure of declined offers risks patient confusion, notification fatigue, and erosion of trust if the clinical context cannot be fully conveyed. Studies of patient communication in transplant settings underscore the importance of timing, framing, and clinician involvement to avoid misinterpretation and distress.[5] The time required for data collection, clinical review and meaningful discussions of questions raised by patients is also likely much greater than CMS estimates.

FAH urges CMS not to include the organ offer notification proposal at this time. Further discussion of this complex issue must occur with the transplant community prior to implementation.

Monitoring and Extreme and Uncontrollable Circumstances

CMS proposes to expand and clarify monitoring activities related to transparency and other IOTA requirements and to update policies related to extreme and uncontrollable circumstances. CMS explains that these changes are intended to strengthen oversight while allowing flexibility in response to emergencies.

FAH requests additional clarification regarding the scope, frequency, and coordination of monitoring activities, particularly in relation to existing oversight by the Organ Procurement & Transplantation Network (OPTN) and other regulatory entities. Monitoring requirements should be narrowly tailored, transparent, and coordinated to avoid duplication and inconsistent expectations.

FAH is also concerned that limiting relief for extreme and uncontrollable circumstances primarily to events associated with Stafford Act declarations may be too restrictive. Transplant programs may experience significant operational disruptions from events beyond their control that do not meet these criteria, including workforce shortages, prolonged supply chain disruptions, and localized infrastructure failures. CMS should retain discretion to mitigate downside risk impacts in such circumstances to ensure fairness and program stability.

Request for Information

CMS requests public input on several aspects of the IOTA Model to inform future refinements, including administrative burden, interaction with existing regulatory frameworks, monitoring approaches, and potential unintended consequences.

FAH appreciates this opportunity and emphasizes that a consistent theme raised by transplant programs concerns the cumulative operational burden associated with the model. While individual requirements may appear reasonable

[5] Gordon, E. J., Mullee, J. O., Ramirez, D. I., & Boulware, L. E. (2019). Patient education and informed decision-making in kidney transplantation. Clinical Journal of the American Society of Nephrology, 14(3), 456–464.

in isolation, their combined effect risks diverting limited resources away from direct patient care and transplant access activities. CMS should assess not only incremental burden but also cumulative impact.

FAH also encourages CMS to consider how IOTA performance measures interact with broader accountability systems. Different measurement frameworks may inadvertently discourage acceptance of higher-risk organs or transplantation of more complex patients. Ongoing stakeholder engagement and transparent communication will be essential to ensure that future refinements are informed by real-world experience.

FAH appreciates CMS's continued engagement and willingness to refine the IOTA Model. We support several proposed changes, including eligibility refinements and the inclusion of risk adjustment in principle. At the same time, we urge CMS to further modify the proposed rule to ensure that quality measurement is clinically valid, financial incentives remain meaningful and administrative requirements do not inadvertently constrain access to kidney transplantation.

FAH stands ready to work with CMS to strengthen the IOTA Model so that it achieves its shared goal of expanding safe, high-quality access to kidney transplantation for Medicare beneficiaries. If you have any questions, please contact Tilithia McBride at tmcbride@fah.org or 202-624-1522.

Sincerely,

Char MacDonald
President and CEO